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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,112	12/29/2003	Sanjay D. Khare	06843.0052-00000	1751

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
07/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,112	KHARE, SANJAY D.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-31,47-62,77-86,104-134 and 153-159* is/are pending in the application.

4a) Of the above claim(s) *16-31, 47-62, 77-86, 105-109, 111-112, 122-134, and 153-159* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *104, 110, and 113 – 121* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of this application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to ILIA OUSPENSKI, Group Art Unit 1644, Technology Center 1600.

2. Applicant's amendment/remarks, filed on 06/01/2007, are acknowledged.

Claims 16-31, 47-62, 77-86, 104-134, and 153-159 are pending.

3. In view of the Restriction Requirement mailed on 09/26/2006, and Applicants election filed on 12/26/2006, claims 16-31, 47-62, 77-86, 105-109, 111-112, 122-134, and 153-159 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions.

Claims 104, 110, and 113 – 121 are under consideration in the instant application.

4. Applicant's election with traverse of Group 58 in the reply filed on 06/01/2007 is acknowledged.

The traversal is on the grounds that the examiner allegedly has not properly accounted for the linking claims which join the claimed inventions.

In response to Applicant's arguments, a modified restriction requirement is set forth herein.

The restriction requirement mailed on 03/01/2007 is hereby vacated.

Restriction Requirement

5. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 113 and 116 – 118, drawn to a method for treating rheumatoid arthritis by administering an AGP3 inhibitor and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

II. Claim 115, drawn to a method for treating rheumatoid arthritis by administering a TACI inhibitor and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

III. Claim 114, drawn to a method for treating rheumatoid arthritis by administering a TACI inhibitor and a BAFFR inhibitor, and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

IV. Claims 113 and 116 – 118, drawn to a method for treating psoriatic arthritis by administering an AGP3 inhibitor and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

V. Claim 115, drawn to a method for treating psoriatic arthritis by administering a TACI inhibitor and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

VI. Claim 114, drawn to a method for treating psoriatic arthritis by administering a TACI inhibitor and a BAFFR inhibitor, and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

VII. Claims 113 and 116 – 118, drawn to a method for treating systemic lupus erythematosus by administering an AGP3 inhibitor and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

VIII. Claim 115, drawn to a method for treating systemic lupus erythematosus by administering a TACI inhibitor and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

IX. Claim 114, drawn to a method for treating systemic lupus erythematosus by administering a TACI inhibitor and a BAFFR inhibitor, and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

X. Claims 113 and 116 – 118, drawn to a method for treating graft rejection by administering an AGP3 inhibitor and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

XI. Claim 115, drawn to a method for treating graft rejection by administering a TACI inhibitor and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

XII. Claim 114, drawn to a method for treating graft rejection by administering a TACI inhibitor and a BAFFR inhibitor, and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

XIII. Claims 113 and 116 – 118, drawn to a method for treating psoriasis by administering an AGP3 inhibitor and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

XIV. Claim 115, drawn to a method for treating psoriasis by administering a TACI inhibitor and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

XV. Claim 114, drawn to a method for treating psoriasis by administering a TACI inhibitor and a BAFFR inhibitor, and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

XVI. Claims 113 and 116 – 118, drawn to a method for treating inflammatory bowel disease by administering an AGP3 inhibitor and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

XVII. Claim 115, drawn to a method for treating inflammatory bowel disease by administering a TACI inhibitor and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

XVIII. Claim 114, drawn to a method for treating inflammatory bowel disease by administering a TACI inhibitor and a BAFFR inhibitor, and a TNF-α inhibitor selected from at least one of etanercept, infliximab, and D2E7, classified in Class 424, subclass 141.1.

Claims 104, 110, and 119 – 121 link inventions I – XVIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. Applicant is advised that if any claims including all the limitations of the allowable linking claim(s) are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Groups I – XVIII are different methods. The methods differ with respect to one or more of ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. The ingredients are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, these methods relate to different pathological conditions which are distinct because they differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. The distinct ingredients, method steps, endpoints and/or pathological conditions require separate and distinct searches. As such, it would be burdensome to search these Inventions together.

7. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Species Election

8. This application contains claims directed to the following patentably distinct Species of the claimed Invention, wherein the TNF-α inhibitor is:

A. etanercept,
B. infliximab, or
C. D2E7.

These species are distinct because their structures, physicochemical properties and mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these Species together.

9. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ilia Ouspenski

ILIA OUSPENSKI, Ph.D.
Patent Examiner
Art Unit 1644

June 25, 2007